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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,868	06/24/2002	Jana Lenz	3868-0112P	6750

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/088,868

Applicant(s)

LENZ ET AL.

Examiner

Christopher L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-27, 41 and 42 is/are rejected.
- 7) ☒ Claim(s) 28-40 and 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. For the purposes of the following art rejections, in view of the various possible combinations of steps in new claim 22, new claim 22 is being considered as follows:

A process for isolating and/or identifying at least one active chemical substance from a non-equimolar mixture of active or inactive chemical substances, comprising the steps:

a.) adding a target to said mixture and forming a complex target and at least one active chemical substance of the mixture;

b.) separating the complex from the inactive chemical substances of the mixture;  
and

c) identifying at least one active chemical substance from the separated complex.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 22-27, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Longoria.

Longoria (US Patent 4,948,726) discloses an enzyme immunoassay for detection of an analyte antigen. A fluid specimen containing the antigen is mixed with enzyme-conjugated antibody specific for the antigen. After a short incubation time, the fluid

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mixture is passed through a filter membrane using positive or negative pressure, or diffusion. The filter is formulated to electrostatically retain the antigen-antibody-conjugate complexes while free antigen or free antibody-conjugate passes through the filter. A substrate-chromogen solution is then applied to the filter or passed through the filter. The substrate-chromogen solution reacts with filter-bound conjugate and color development occurs on the membrane (col. 3, lines 38-63). Buffers for use in the method are selected for optimum performance with the enzyme, substrate, and filter paper system in use. Buffering agents are selected from phosphate, tris, glycine, citric acid, and sodium acetate. Depending on the particular application, buffers may range in molarity from about 0.001 M to about 0.3 M and may range in pH from about pH 3.5 to about pH 10 (col. 5, lines 9-26).

In the method of Longoria, the enzyme-conjugated antibody reads on the "target" in step (a) of claim 22. Contacting the sample with enzyme-conjugated antibodies to form antigen-antibody-conjugate complexes reads on step (a) of claim 22. The separation of complexes with the filter membrane reads on step (b) of claim 22. And the application of substrate-chromogen to the filter membrane to identify bound antigen reads on step (c) of claim 22. Example 1 of Longoria shows assaying a human serum sample, which can contain a non-equimolar mixture of active or inactive chemical substances.

With respect to claims 26 and 27, the antigen-antibody bond between the analyte antigen and antibody of the conjugate is considered a non-covalent bond.

***Allowable Subject Matter***

4. Claims 28-40 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin  
Primary Examiner  
Art Unit 1641

5/31/05